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**From:** Wozniak, Chris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8287E326F7A148FB9870D5D79333DEBC-CHRIS WOZNIAK]  
**Sent:** 12/14/2016 9:22:15 PM  
**To:** Evdokimov, Evgenij A [Evgenij.Evdokimov@fda.hhs.gov]  
**Subject:** RE: Oxitec update

Great! I have a Drs appt early Friday but will call you when I get in around 10:30 or so.....

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**From:** Evdokimov, Evgenij A [mailto:Evgenij.Evdokimov@fda.hhs.gov]  
**Sent:** Wednesday, December 14, 2016 4:21 PM  
**To:** Wozniak, Chris <wozniak.chris@epa.gov>  
**Subject:** RE: Oxitec update

Sure, I am here Thursday and Friday. I have a few meetings on Thursday, so the best time for me would be between 10:30 – noon. Friday is open until noon as well. I will be out of the office next two weeks. Let me know what time is the most convenient for you.

Evgenij

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**From:** Wozniak, Chris [mailto:wozniak.chris@epa.gov]  
**Sent:** Wednesday, December 14, 2016 4:16 PM  
**To:** Evdokimov, Evgenij A  
**Subject:** RE: Oxitec update

Evgenij,

Thanks for the update! Are you around later tomorrow or Friday? I have a small matter I wanted to relate to you and best over the phone.

Chris

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**From:** Evdokimov, Evgenij A [mailto:Evgenij.Evdokimov@fda.hhs.gov]  
**Sent:** Wednesday, December 14, 2016 9:09 AM  
**To:** Wozniak, Chris <wozniak.chris@epa.gov>; McAllister, Janet C (CDC) <jvm6@cdc.gov>  
**Cc:** Dass, Brinda <Brinda.Dass@fda.hhs.gov>  
**Subject:** Oxitec update

Dear colleagues,

I just wanted to give you an update on the latest developments with Oxitec. Recently, Oxitec proposed to conduct an investigational study or studies in one or more other locations of Monroe County, FL. In support of this proposal, the sponsor submitted an EA for investigational use of OX513A mosquitoes for all of Monroe County, FL. CVM's preliminary review established that the sponsor's EA does not include relevant information about Monroe County, FL. Examples of missing information include but are not limited to potential sources of tetracycline in the environment, (e.g., presence of hospitals, waste water treatment facilities, farms, etc.), information on all Monroe County national parks/national wildlife refuges and endangered species and how they might be impacted by the proposed trial and trial site location(s), and ranges of numbers of Oxitec male mosquitoes that potentially would be released at the trial site(s), including how those numbers affect the number of females that could be released and how those numbers affect the assessment of potential risk to humans and other animals including that related to bites. The Monroe County EA is also missing other site-specific information comparable to the site-specific

information included in FDA's final Key Haven EA. Therefore, we concluded that their submission is incomplete and we requested that the sponsor provides necessary information in their re-submission.

Please let Brinda or me know if you have any additional questions.

Thank you,

Evgenij

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